



Integrated Science Assessments

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Clean Air Act Requirements

Section 108 of the Clean Air Act requires “**issuance of air quality criteria**” that includes information on “...the **kind and extent of all identifiable effects on public health or welfare** which may be expected from the presence of [the pollutant] in the ambient air...”.

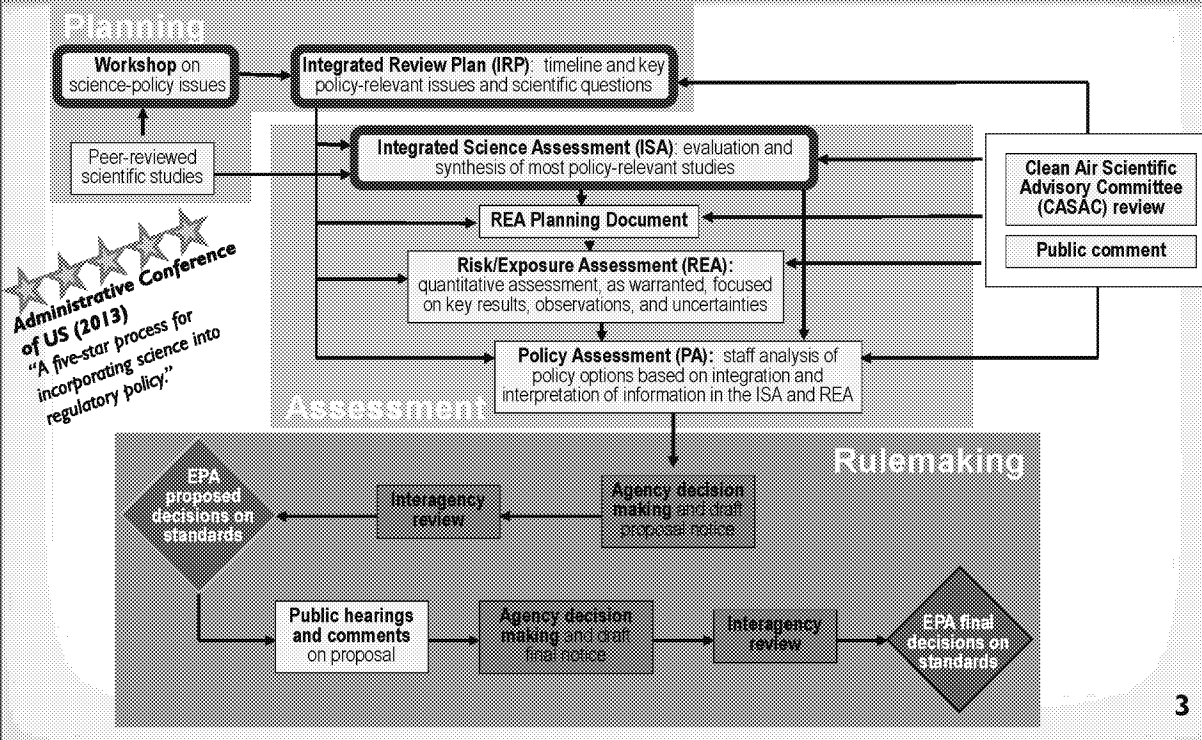
The six criteria air pollutants are: ozone (O₃) particulate matter (PM), sulfur oxides (SO_x), nitrogen oxides (NO_x), lead (Pb), and carbon monoxide

Section 109 of the Clean Air Act requires for “...any air pollutant for which air quality criteria are issued...” the promulgation of “...national primary ambient air quality standards...requisite to protect the public health...” and “...national secondary ambient air quality standard[s]...requisite to protect the public welfare”.

The Administrator is charged with promulgating the standards and OAR develops the proposed and final rules with scientific input from ORD.



NAAQS Review Flowchart





The Integrated Science Assessments



- Concise evaluation and synthesis of the most policy-relevant science
- Emphasis on integration of the science and on clear characterization of strengths and uncertainties of available scientific evidence
- **ISA provides the scientific foundation for:**
 - Risk and Exposure Assessment (REA), if warranted
 - Policy Assessment (PA)
 - **Agency decisions as reflected in proposed and final NAAQS rulemaking**
- CASAC reviews the ISA drafts and other documents listed above
 - Public meetings announced in the Federal Register with solicitation for public comments



The ISA Development Process

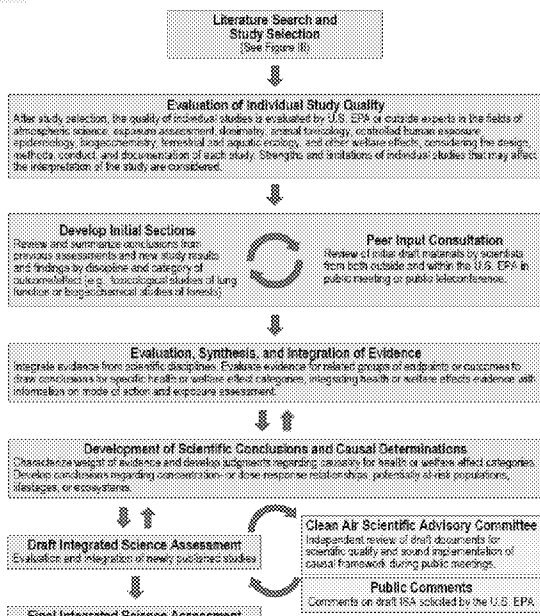


Figure II of the Preamble to the ISA

- Fundamental process:
 - Literature search and study selection
 - Evaluation of individual study quality
 - Evaluation, synthesis, and integration of evidence
 - Development of scientific conclusions and causal determinations
- Several layers of review:
 - Peer input
 - Clean Air Scientific Advisory Committee
 - Public comments
- Typical review cycle includes two drafts and then Final ISA
- **Impact of May 2018 Administrator memo: current PM and Ozone reviews limited to one draft**



Recent Literature Reviews

ISA	Screened	Considered	Included
PM – Health and Welfare Criteria 1 st External Review Draft	310,094	5,194	2,655
NO _x SO _x PM – Ecological Criteria 1 st External Review Draft	231,828	~6,000	3,319
SO _x – Health Criteria 2 nd External Review Draft	56,502	1,522	999
NO _x – Health Criteria Final Report	246,817	5,466	1,680
O ₃ – Health and Welfare Criteria Final Report	Not recorded	4,044	2,276
Pb – Health and Ecological Criteria Final Report	~500,000	7,398	3,189



• Laboratory studies

- More subtle effects easier to detect
- Limited range of responses and pollutant bioavailability
- Large scale processes difficult to reproduce

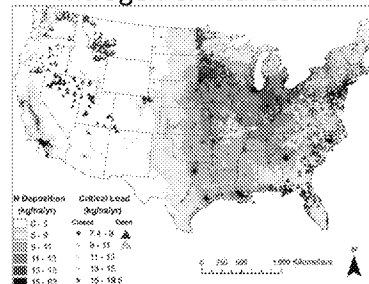
• Field observational studies

- High natural variability
- Possible to assess multiple stressors or site-specific factors
- Larger geographic scales or higher levels of biological organization
- Most effective when stressors and effects are measured concurrently

• Manipulated natural environments

- Some sources of response variation are removed through control conditions
- Some sources of response variation included to mimic natural variation
- More controlled than field observational studies
- Less tightly controlled than laboratory studies

Nitrogen Critical Loads



- Promote consistency and transparency
- Emphasize synthesis of evidence across scientific disciplines
- **Weight of evidence categories:**
 - Causal relationship
 - Likely to be a causal relationship
 - Suggestive of, but not sufficient to infer, a causal relationship
 - Inadequate to infer a causal relationship
 - Not likely to be a causal relationship
- ISA Preamble describes this framework
 - Preamble is now stand-alone document (<http://www.epa.gov/isa>)
- **CASAC has supported use of this framework**



Causality Determinations: Human Health Effects

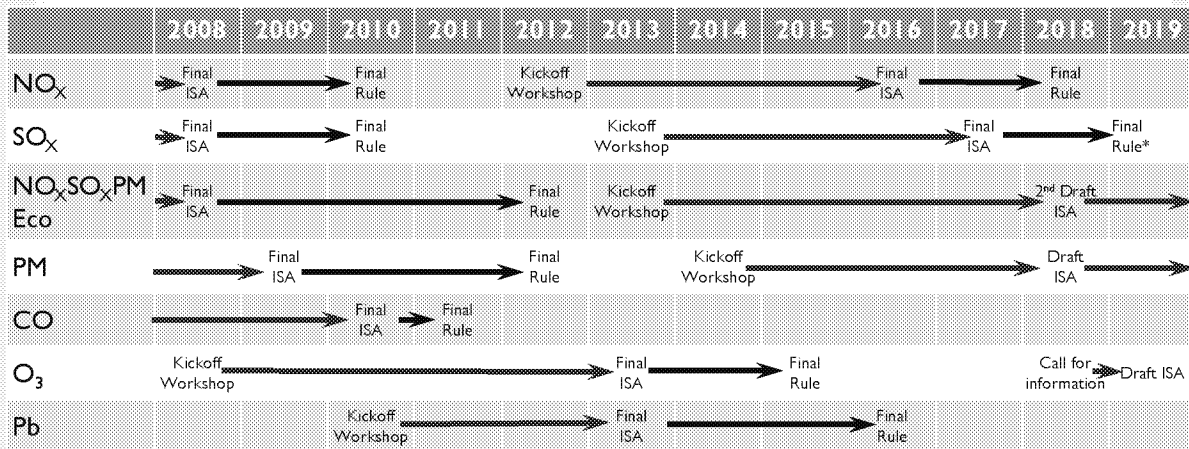
HUMAN HEALTH EFFECTS								
ISA		2017 SO _x Health	2016 NO _x Health	2013 O ₃	2019 CO	2009 PM		
Indicator		SO _x	NO _x	O ₃	CO	PM _{2.5}	PM _{10-2.5}	LFP
Health Outcome	Mortality	Short-term exposure						
		Long-term exposure						
	Respiratory	Short-term exposure						
		Long-term exposure						
	Cardiovascular	Short-term exposure						
		Long-term exposure	Missing Data					
	Reproductive	Fertility, pregnancy, and reproduction						
		Birth outcomes						
		Developmental outcomes						
	Cancer	Long-term exposure						
	Central nervous system	Short-term exposure						
		Long-term exposure						

Causal
 Likely causal
 Suggestive
 Inadequate
 Not likely
 Not evaluated in causal framework



ISA History and Progress

“All NAAQS All the Time”



*Final rule signature for SO_x by January 28, 2019 by consent decree



Issues for Discussion

* **May 9 2018 Memorandum: "Back to Basics Process for Reviewing the NAAQS"**

- Accelerate ozone and PM NAAQS reviews; to be completed by December 2020
 - Much less time for ISA development, review, and subsequent NAAQS decision making
 - One draft for CASAC review
- Resources critically limited; same staff working on 3 ISAs at same time (PM, Ozone, NOx/SOx/PM-Eco)
- NOx/SOx/PM-Eco ISA CASAC review meeting held Sept 5-6 2018
- PM Draft ISA review – December 2018

* **Ozone ISA**

- Started ISA development in May 2018; eliminated "kickoff" workshop
- ISA schedule is integrated with OAR activities (Policy Assessment, Proposed and Final NAAQS)
- Extremely tight schedule, no room for slippage

* **CASAC**

- Membership uncertain
- Timing for PM and Ozone